UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,715	08/14/2001	Moncef Jendoubi	266/226	1686

34313 7590 05/28/2003

ORRICK, HERRINGTON & SUTCLIFFE, LLP
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	11

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,715	JENDOUBI, MONCEF	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 3/18/03 in Paper No. 10 is acknowledged and entered. Claims 12-13 are canceled by the amendment. Claims 1 and 3 are amended by the amendment.

2. Claims 1-11 are pending.

Withdrawn Rejections

3. The previous rejections 35 USC 112, first and second paragraph, for claims 12-13 have been withdrawn in view of applicant's cancellations of claims 12-13.

4. The previous rejections 35 USC 112, second paragraph, for claims 1-11 have been withdrawn in view of applicant's amendments of claims 1 and 3.

5. The previous rejections under 35 USC 103(a) as being obvious over Iris et al. (US Patent 6,403,309 B1) in view of Bandaru (US Patent 6,462,187 B1) for claims 1 and 3 have been withdrawn in view of applicant's amendments of claim 3.

6. Claims 1-11 are treated on the merit in this Office Action.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

8. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Iris et al. (US Patent 6,403,309 B1). ***(Note: the amended claim 3 would now be included in this rejection)***

Iris et al. discloses a method that utilizes oligonucleotide probes labeled with distinguishable and identifiable labels, (e.g. peptide tags), that are captured on addressable antibody arrays for analysis (col. 1, lines 14-18). The method can be use for the analysis of gene expression (refers to instant claim 1) using addressable antibody array (col. 14, lines 51-67). The method is used to directly monitor qualitative and quantitative gene expression levels in tissue biopsies or histological preparations that is taken from patient with suspected genetic disorder. The RNA target is extracted from the tissue sample and hybridized with the oligonucleotide probes (col. 15, lines 32-67 to col. 16, lines 1-11). The sample is then exposed to a solid phase surface, which would be an addressable antibody arrays, comprising a binding partner to the peptide label oligonucleotide probe. The solid phase surface comprises a plurality of loci, wherein each locus comprises an antibody specific to one or more of the peptides of the peptide label oligonucleotide probes (col. 6, lines 28-31; col. 22, lines 23-29). The antibodies includes polyclonal or monoclonal (refers to instant claim 2) (col. 23, lines 33-57). The polyclonal antibodies are produce from mice or rat. The detection of a signal would indicate the present of the target RNA (col. 16, lines 12-19). Additionally, the method can be used for multiplex screening to phenotype/genotype association analysis (col. 14, lines 24-33). A target DNA sample comprises a plurality of DNA molecules derived from a population of individuals afflicted with a disorder such as cancer. A control DNA sample comprises of DNA molecules

derived from a non-afflicted populations. The two populations can be screened in multiplex with a number of peptide label oligonucleotide probes, and the results compared between the two populations. The method of Iris et al. anticipated the method of the claimed invention.

New Rejections – Necessitated by Amendment

Claim Objections

9. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The amended claim 3 recites *'the method of claim 1 wherein the step of contacting the plurality of samples is performed with the antibody'* is the same as the "contacting" step of claim 1 that recites '*contacting each of the plurality of the samples with an antibody'*. Therefore, claim 3 does not further limit the claim 1.

10. Claim 3 is objected to because of the following informalities: the amended claim 3 is grammatically incorrect that is "the plurality of samples is performed with the antibody is performed with antibodies obtained." Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claimed method to analyze gene expression recites the followings method steps:

a) providing a plurality of samples of biological material comprising a polypeptide and

b) contained in discrete compartments as separate samples from at least two distinct biological conditions

c) contacting each of the plurality of samples with an antibody wherein the antibody has been obtained by an immune response to in vivo expression of a gene sequence

d) correlating the reaction between the antibody and the plurality of samples with expression of the gene sequence in the samples.

The recitation of 'a plurality of samples of biological material comprising a polypeptide' claimed in claim 1, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed '*The matrix protein arrays comprise a group of individual total protein extracts, which group comprises at least two distinct samples of total protein extracts*' (lines 3-4) is not support for 'a plurality of samples of biological material comprising a polypeptide'. Because the specification recites a group of individual total protein extracts (genus), does not support the limitation of the claim, which recites a polypeptide (species). That is a genus (total protein extracts) is not descriptive in defining a specific species (a polypeptide). Therefore, the scope of the invention as originally disclosed in the specification would not

encompass the scope of the limitation of a plurality of samples of biological material comprising a polypeptide.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

13. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claimed method step of claim 3 recites wherein the step of contacting the plurality of samples is performed with antibodies obtained from the in vivo expression of at least 100 different gene sequences.

The recitation of 'antibodies obtained from the in vivo expression of at least 100 different gene sequences' claimed in claim 3, have no clear support in the specification and the claims as originally filed. The specification in page 8 disclosed '"Monoclonal antibodies" are substantially homogenous populations of antibodies to a particular antigen. They may be obtained by any technique that leads to the production of antibody molecules by continuous cell lines in culture. Monoclonal antibodies may be obtained by methods known to those skilled in the art. See, for example, Kohler, et al., Nature 256:495-497 (1975), and U.S. Pat. No. 4,376,110. The term "polyclonal" refers to antibodies that are heterogeneous populations of antibody molecules derived from the sera of animals immunized with an antigen or an antigenic functional derivative thereof. For the production of polyclonal antibodies, various host animals

may be immunized by injection with antigen. Various adjuvants may be used to increase the immunological response, depending on the host species' (lines 8-17) is not support for 'antibodies obtained from the in vivo expression of at least 100 different gene sequences'. Because the narrow limitation of the specification recites 'monoclonal antibodies' and 'polyclonal antibodies', does not support the broad limitation of the claim 3, which recites antibodies obtained from the in vivo expression of at least 100 different gene sequences. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of antibodies obtained from the in vivo expression of at least 100 different gene sequences.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Response to Arguments

14. Applicant's arguments in view of the rejection under 35 U.S.C. 102(e) of Claims 1-2 and 4-11 as being anticipated by Iris et al. (US Patent 6,403,309 B1) filed on 3/18/03 have been fully considered but they are not persuasive.

Applicant contends that Iris et al. does not disclosed gene expression profiling using a polypeptide product and does not refer to antibodies created by in vivo expression.

It is the examiner position that Iris et al. do disclosed gene expression profiling using a polypeptide product. Iris et al. disclose that 'in another embodiment of the invention, methods are provided to monitor gene expression events both qualitatively and quantitatively using peptide-labeled oligonucleotide probes (polypeptide product) and addressable array analysis (col.

14, lines 53-56) and an addressable array, as used in the invention, comprises a plurality of distinct polypeptides attached to precise locations on a solid phase surface, such as a plastic chip (col. 22, lines 23-25)'. Therefore, Iris et al. do disclosed gene expression profiling using a polypeptide product.

Further, the antibodies described by Iris et al. are the "same" as those described by specification of the instant claimed method. Iris et al. disclose that '*monoclonal antibodies, which may be used with the invention, are homogeneous populations of antibodies to a particular antigen. A monoclonal antibody (mAb) to an antigen-of-interest can be prepared by using any technique known in the art, which provides for the production of antibody molecules by continuous cell lines in culture. These include but are not limited to the hybridoma technique originally described by Kohler and Milstein (1975, Nature 256: 495-497)*' (col. 23, lines 66-67 to col. 24, lines 1-7). '*Polyclonal antibodies, which may be used with the invention, are heterogeneous populations of antibody molecules derived from the sera of immunized animals. Various procedures well known in the art may be used for the production of polyclonal antibodies to an antigen-of-interest. For example, the production of polyclonal antibodies, various host animals can be immunized by injection with an antigen of interest or derivative thereof, including but not limited to rabbits, mice, rats, etc. Various adjuvants may be used to increase the immunological response, depending on the host species*' (col. 23, lines 49-59). These descriptions of both monoclonal and polyclonal antibodies are the same as those describe in the specification of the instant claimed method. The specification in page 8 disclosed '*"Monoclonal antibodies" are substantially homogenous populations of antibodies to a particular antigen. They may be obtained by any technique that leads to the production of*

antibody molecules by continuous cell lines in culture. Monoclonal antibodies may be obtained by methods known to those skilled in the art. See, for example, Kohler, et al., Nature 256:495-497 (1975), and U.S. Pat. No. 4,376,110. The term "polyclonal" refers to antibodies that are heterogeneous populations of antibody molecules derived from the sera of animals immunized with an antigen or an antigenic functional derivative thereof. For the production of polyclonal antibodies, various host animals may be immunized by injection with antigen. Various adjuvants may be used to increase the immunological response, depending on the host species' (lines 8-17). Therefore, the antibodies of Iris et al. would refer to the antibody of the instant claim 1 that is the created by in vivo expression process.

Additionally, the limitation of "wherein the antibody has been obtained by an immune response to in vivo expression of a gene sequence" in claim 1 and the limitation of "antibodies obtained from the in vivo expression of at least 100 different gene sequence" in claim 3 are written as a product-by-process limitation (e.g. antibody is a product of an in vivo process). "Eventhough the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does hot depend on its method of production. If the product in the product-by-process claims is same or as obvious from the product of the prior art, the claim is unpatentable eventhough the prior art product was made by a different process." *In re* Thorpe, 777 F. 2d 695, 698, 227 U. S. P. Q. 964, 966 (Fed. Cir. 1985). (see MPEP 2113). Therefore, the antibody use in the presently claimed method is the same as or obvious from the antibody of Iris et al.

The amended claim 3 is included in this rejection because the new limitation of "antibodies obtained from the in vivo expression of at least 100 different gene sequence" is a product-by-process limitation, which bears no patentable weight. Therefore, claim 3 fails to further limit claim 1.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
May 23, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER